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(54) Methods of making dressings

(57) Medical dressings are made by use of packages which may be held in the hand, and which contain the components of two part room temperature curable polysiloxane foam compositions in such a manner that the component may be mixed in predetermined proportions and dispensed therefrom under the influence of propellant gas.

The method avoids the need for manual mixing of such compositions during production of dressings.

FIG.:2

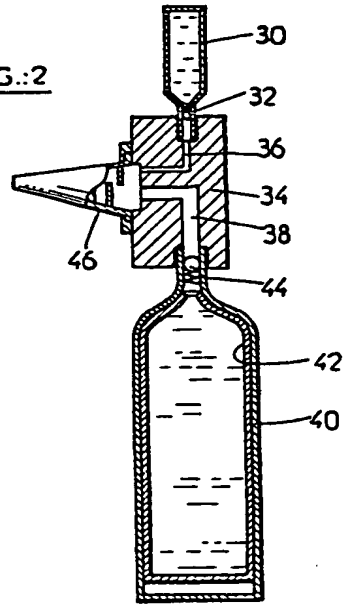

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FIG.:1

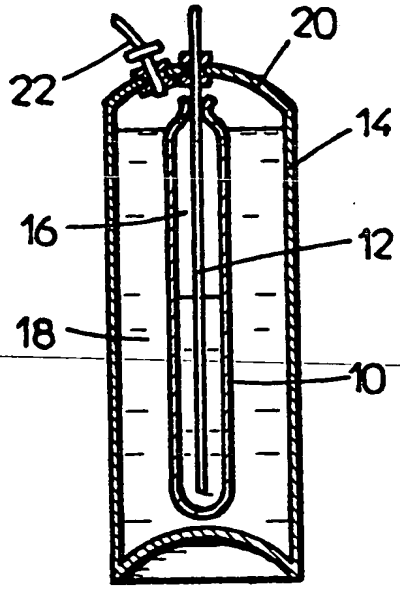
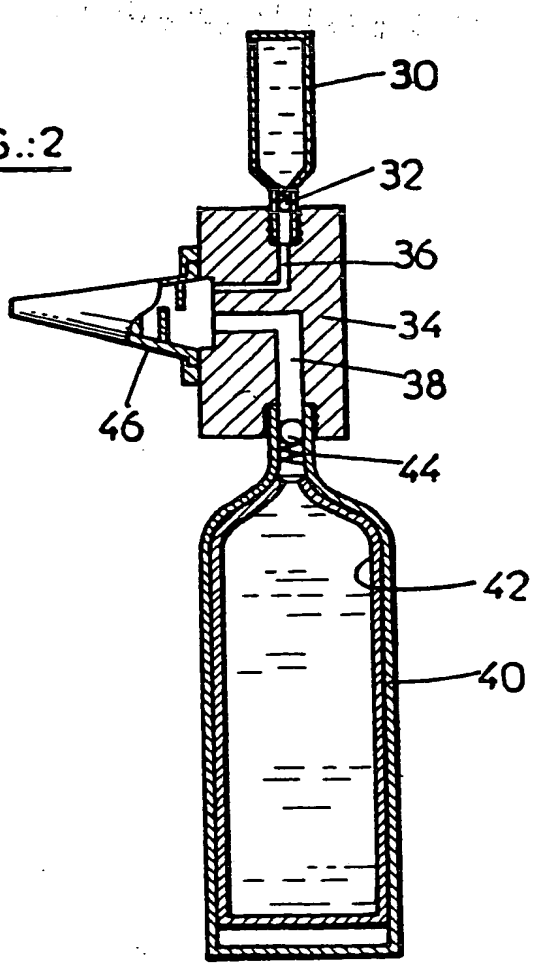
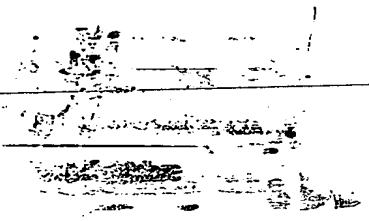


FIG.:2





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SPECIFICATION

Methods of making dressings

This invention is concerned with making dressings i.e. dressings for surgical or medical treatment of the human and animal body.

It has been proposed to employ two-part curable organosiloxane compositions for preparing of dressings. For example G.B. patent specification 1 492 581 describes dressing for open granulating wounds made by a process in which the two parts of a composition are mixed and then poured into an open wound where the composition cures to provide an elastomeric dressing. Compositions proposed for making such dressings have comprised poly(dimethylsiloxane) and finely divided filler base or "part A", and a catalyst part or "part B" comprising catalyst material for promoting room temperature curing and foaming of the composition according to the scheme $\equiv SiOH + HSi\equiv \rightarrow \equiv Si-O-Si\equiv + H_2$. By use of these compositions one may provide comfortable, non-adherent dressings conforming to the contours of the wound which are *inter alia* soft, resilient, permeable to air and somewhat absorbent.

Such a procedure for producing dressings lead to a variety of advantages related to improved patient comfort e.g. resulting from the non-adherent characteristics of the dressing and reduced care from nursing staff e.g. due to the increased possibility for the patient to remove the dressing to permit washing and/or disinfecting of the wound and dressing, followed by replacement of the dressing.

The correct use of two component compositions entails correct proportioning of the components and adequate mixing thereof. Adequate mixing of components of different viscosities can prove tedious when manual methods are used, but in general hand mixing of two part compositions or their component parts may be carried out by use of a suitable stirring implement for example a spatula. However, apart from the tedium involved, such mixing may lead to entrapment of air bubbles in the compositions. Particularly in those cases where more viscous compositions or faster curing compositions are used, these bubbles may become trapped in the composition as it cures. Entrapped bubbles in dressings produced render the dressings non-uniform and thus of variable quality. This is generally undesirable and in some cases may be wholly unacceptable. In addition, exposure of the composition to the environment during mixing to produce dressings in undesirable as it may be unhygienic in view of the possibility of contaminating the dressing as it is produced.

Apart from the desirability of mixing together the components without exposure to the atmosphere, those compositions which have been proposed for use in accordance with G.B. 1 492 581 tend to require separate mixing of the part A prior to admixture of the parts A and B. In the proposed compositions separation of the filler from the other components may occur during storage.

Thus, the step of mixing the part A of the composition just prior to use is a critical step. When this step, or the proportioning of ingredients is not carried out adequately or at all (as may happen in practice) poor quality dressings result.

It is troublesome to rectify improper mixing of such compositions because very often the fact of improper mixing is not recognised until after the supposedly curing composition has been applied to its allotted position. After recognition of failure to provide a suitably cured mass it becomes desirable to remove the defective material, clean up the site and to acheive the desired result by correct application or by some other practice. Such remedial operations are troublesome and inconvenient and are especially so in those cases where the product is used to provide a treatment for an open wound for example on the human body.

It is common practice to package materials in so-called aerosol form particularly for surface coating applications. Materials which are usually packaged in this way consists primarily of liquids or solutions of comparatively low viscosity and which essentially do not require mixing with another ingredient prior to ejection from the package. Proposals have been made to extend the use of aerosol type packaging to curable two-part compositions. For example in G.B. specification 861448 there is described and claimed a package comprising a pressure tight container having a closeable outlet orifice and containing a polymerizable material of such a nature that it will convert at a temperature below approximately 150°F (65°C) rapidly and completely to an organic polymer only when released from said outlet orifice, and a propellant that is gaseous at room temperature and pressure, said propellant being present in a sufficient quantity and being capable of exerting a sufficient pressure within the container to expel said polymerizable material through said orifice. In a preferred form of construction an agent for activating polymerization is maintained with a volatile propellant physically separated from the polymerizable material in a compartment from which it may be expelled through an orifice into a mixing chamber wherein said polymerizable material and said activator are blended under reduced pressure prior t being expelled to the atmospher .

The applicant has found it impossible satisfactorily to package certain curable polysiloxane compositions using known aerosol type packages. There exists a particular problem of packaging filled materials which have a consistency which is thicker than the liquid polysiloxane fluids and these materials are among thos which are particularly beneficial f r the pr duction of dressings.

It is one of the objects of the present invention t provide an improved meth d of making a dressing.

Th applicant has now found that a dressing i.e. a mass conforming to the contours of a wound or body and which is *inter alia* non-adherent, permeable to air and preferably resilient and somewhat absorbent, may be readily produced by use of a two compartment package containing selected tw component polysiloxane

compositions.

The invention provides in one of its aspects a method of making a medical dressing by use of a room temperature curable polysiloxane composition comprising two component parts which together provide an organosilicon polymer including siloxane units providing a silicon-bonded hydroxyl group, an organosilicon polymer including siloxane units having a silicon-bonded hydrogen atom, filler material and catalyst, the organosilicon polymers being such that they are capable of chemical reaction at room temperature when mixed in the presence of the catalyst whereby hydrogen is evolved to cause the composition to foam and the composition becomes cured thus to provide a resilient polysiloxane foam mass which method comprises procuring a package comprising two compartments each of which contains one of the component parts of the composition and from which the component may be expelled by means of propellant gas, in which package the filler material comprises finely divided hydrophobic filler and at least one of the components also contains a material intended to provide a propellant gas, the package being so constructed and arranged that it may be operated to mix predetermined proportions of the components in the absence of air and to dispense the mixed composition from the package, the method also comprising operating the package to bring about mixing of the components in said predetermined proportions and dispensing the mixed composition from the package to provide said dressing in desired shape.

Compositions suitable for use in a method according to the invention preferably are capable upon admixture of their component parts of becoming cured in a short time at room temperature to provide a silysiloxane mass. For many purposes, a composition curable within a few minutes at temperatures in the range of about 15°C to 30°C without application of heat is desirable. Such compositions may comprise parts A and B of similar or different viscosities and providing components of the curable composition which are interactive or catalytic one with the other and thus stored separated to avoid premature cure.

Alkylhydrogen polysiloxanes and hydroxypolysiloxanes and catalysts for promoting their reaction to provide cured foams may be for example generally as disclosed in G.B. Patent Specifications 798 669 and 867 619.

Suitable organosilicon polymers having a silicon-bonded hydrogen atom for use in the invention include alkylhydrogen polysiloxanes having units according to the general formula

$$R_pH_qSiO_{\frac{4-(p+q)}{2}}$$

in which each R represents a lower alkyl or phenyl radical e.g. a methyl radical, p is 0, 1 or 2, q is 1 or 2 and the sum of p and q is 1, 2 or 3. The alkylhydrogen polysiloxanes may also comprise units

$$R_nSiO_{\frac{4-n}{2}}$$

in which R is as defined above and n has the value 1, 2 or 3. Curing reactions of the preferred compositions are dependent on the presence of appropriate proportions of the inter active silicon-bonded substituents and the alkylhydrogen polysiloxane may be selected accordingly. We prefer that each R represents a methyl group. Preferably, terminal groups of the alkylhydrogen polysiloxane are $R_3SiO_{1/2}$ groups where each R represents a methyl group. Suitable alkylhydrogen polysiloxanes include those comprising predominantly MeHSiO units with or without the presence of Me_2SiO and having viscosities of the order of from about 0.001 to about 0.1 Pa.s, preferably 0.001 to 0.05 Pa.s at 25°C.

Suitable organosilicon polymers having silicon-bonded hydroxyl groups include hydroxy polysiloxanes having units according to the general formula

$$R_m(OH)SiO_{\frac{3-m}{2}}$$

in which each R represents a lower alkyl or phenyl radical e.g a methyl radical and m is 1 or 2. These polysiloxanes also comprise units

$$R_nSiO_{\frac{4-n}{2}}$$

in which R is as defined above and n is 1, 2 or 3. These materials are preferably liquids and are chosen so that their functionality is appropriate in relation to the degree of chain extension and crosslinking required during curing of the composition. We prefer to employ polysiloxanes which are essentially difunctional i.e. α,ω, di-hydroxy polysiloxanes having a viscosity of about 0.5 to 25 Pa.s at 25°C i.e. a number average molecular weight of the order of about 20,000 to about 80,000. Preferred materials have viscosities of the order of about 1.5 to about 15 Pa.s at 25°C and the most preferred materials have viscosities of about 1.8 to 2.6 Pa.s. The preferred material comprise per molecule, primarily units according to the general formula R_2SiO and two

units according to the general formula $R_2(OH)SiO_{1/2}$. In the preferred materials, the R groups are predominantly methyl radicals. In preferred compositions according to the invention, the preferred hydroxy functional polysiloxanes thus provide polysiloxane chains or significant length and this is desirable in view of flexibility and elastomeric properties required of the product resulting from curing of the composition. If desired, comparatively low molecular weight i.e. short chained organofunctional polysiloxanes may also be included in the composition. Suitable materials include α, ω, polysiloxane diols having up to twenty five dimethylsiloxane units in the molecular chain.

Fillers suitable for use in the invention comprise hydrophobic materials which may be prepared by treatment of finely divided silica with organosilanes, organosiloxanes, organosilazanes or alkylsilanols. Suitable organosilanes include those represented by the general formula $(R)_aSi(X)_b$ in which each R represents a lower alkyl or aryl radical for example a methyl radical, each X represents a hydroxyl radical or halogen atom for example Cl or Br, and each of *a* and *b* is 1, 2 or 3 and $a + b = 4$. Examples of such materials include trimethyl monochlorosilane, dimethyl dichlorosilane and trimethyl monohydroxysilane. The hydroxysilanes may be produced for example by hydrolysis of appropriate alkyl disilazanes; for example one preferred filler material is a reaction produce derived from silica and hexamethyldisilazane in presence of water. Suitable filler materials have a surface area between about 50 and about 300 m^2/g and preferred materials have a surface area between about 100 and about 250 m^2/g. These hydrophobic fillers may be prepared for example by addition to the silica and alkyldisilazane. They are prepared in a separate operation and the hydrophobic filler is added to the other ingredients of the composition.

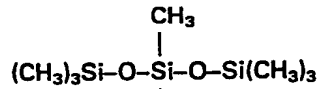
If desired, untreated finely divided filler materials may also be included in the composition in amounts which do not lead to undesirable settlement of the filler in the composition during storage prior to curing. Suitable fillers include metal oxides, clays and silicas.

The organosilicon polymers are such that they are capable of chemical reaction at room temperature when mixed in presence of the catalyst. For many purposes, a composition curable within a few minutes at temperatures in the range of abuot 15°C to about 30°C without application of heat is desirable. Tin compounds suitable for use as catalyst in a composition according to the invention include tin salts of carboxylic acids and particularly tha stannous salts of the more commonly available carboxylic acids. Examples of suitable materials are dibutyl tin dilaurate, stannous acetate, stannous napthenate, stannous benzoate, stannous sebacate, stannous succinate and stannous octoate.

It is also desirable to include in the composition appropriate quantities of higher functional materials as crosslinking agents. Suitable crosslinking agents include materials having three or more functional e.g. hydroxy groups per molecule. Preferred foam forming compositions include an alkoxysilane and/or a condensation product thereof capable of combining with three or more hydroxy polysiloxane molecules with release of the corresponding alcohol of the alkyl radicals, e.g. methyl trimethoxysilane, n-propylorthosilicate and ethyl polysilicate.

Compositions for use in the invention preferably include monofunctional hydroxy silicon compounds effective as chain terminators. Such materials influence the structure of foams formed by use of the composition and their use is highly preferred where predominantly "open-cell" foams are desired. Suitable monofunctional hydroxy compounds include triorganosilanols and organosiloxanols which may be for example short chain siloxanes having for example up to about 25 siloxane units per molecule and having a terminal or pendant hydroxyl group, or a material of the general formula R_3SiOH where each R may be for example a lower alkyl group e.g. a methyl group or a phenyl group. Examples of such materials include

$HO(CH_3)_2Si(OSi(CH_3)_2)_3CH_3$ (nonamethyl tetrasiloxane-1-ol)



(heptamethyltrisiloxan-2-ol)

and

$CH_3(C_6H_5)_2SiOH$ (diphenylmethylsilanol)

Quantities of th various materials employed must be varied within comparatively wide ranges without departing from the spirit of the invention. However, in order to obtain elastom ric foams of densities between about 120 and about 210 kg/m^3 within 3 minutes of mixing the ingredients at room temperature we prefer to employ various preferred materials in amounts within ranges as follows:

Material	*Parts by Weight*	
	Preferred Amounts	*More Preferred Amounts*
αω, di-hydroxy polysiloxanes viscosity 1.8 to 2.6 Pa.s	100	100
Low mw hydroxy polysiloxane	0-60	5-20
Alkylhydrogen polysiloxane	8-35	10-30
Crosslinking agent	0-7	3-5
Filler	5-35	5-15

Catalyst 3 to 8% by weight based on the weight of the above formulations.

Packages for use in the invention have two compartments or chambers from which chambers for components may be expelled by means of propellant gas. The propellant gas may be expelled from the compartment together with the component. Alternatively, the expulsion is effected by a membrane within the chamber which membrane is capable of acting upon the composition under the influence of propellant located between the membrane and a surface of the chamber, so that it is not expelled from the chamber with the composition.

Suitable propellants for admixture with the composition are inert to the ingredients, do not adversely affect the product and preferably are soluble in the composition. For many purposes, nitrogen and the liquefied gases known for use in aerosols are suitable including hydrocarbons for example methane, ethylene, ethane, propane, neopentane and the many halogenated hydrocarbons especially the fluorinated hydrocarbons, for example methyl fluoride, trifluoromethane, monochlorodifluoromethane and dichlorodifluoromethane.

The chambers of the package may be arranged one within the other or one adjacent the other and the construction and arrangement is such that the package may be operated so that the composition is dispensed from the package with its components mixed in air free conditions in predetermined proportions. Preferably the package has a mixer nozzle through which the component parts of the composition may be passed to mix them together. The second chamber may be of a construction which is different from the first mentioned chamber. It is essential that one of the components of the foam forming composition contains admixed propellant gas as aforesaid. In those cases where it is necessary to mix small proportions of one component with large proportions of the other, or where one of the components is of substantially lower viscosity than the other, we prefer to package the component which is to be used in smaller quantities, or that which is less viscous, for expulsion from its chamber together with propellant gas. The chambers may be arranged to dispense single, or more preferably multiple, doses per package as desired. Plastics, metal or glass moisture proof chambers are preferably used.

A package for use in the invention may comprise for example two chambers one within the other. Thus, one component of the composition (e.g. the part A) may be stored in an outer compartment of the package and the other may be stored in an inner compartment of the package together with compressed propellant gas. When required for use, the materials from the inner compartment may be allowed to intermingle with the materials of the outer compartment, the component mixed e.g. by thorough shaking and the whole dispensed from the package under pressure of the propellant gas. In another arrangement, the package may comprise two adjacent compartments each containing a component part of the composition. One or each component part may comprise organopolysiloxane and hydrophobic filler. These compartments may be arranged and adapted to discharge their contents in desired proportions via a manifold to a mixing nozzle when required, seriatum until the compartments have been emptied.

Packages for use in the invention preferably are designed for simple manual operation and may contain sufficient composition for use in those situations where comparatively small quantities of composition are likely to be required at any particular time. Advantages of the invention are particularly beneficial when it is important to ensure suitable admixture of the parts of the composition with minimal operator attention, and where contamination of the composition by air entrapment and/or otherwise is to be avoided.

By use of the invention one can avoid the need for hand mixing of dressing compositions and one can produce surgical and medical dressings which are non-adherent to wounds, permeable to air, slightly absorbent and slightly permeable to moisture and which may have bacteriostat properties. The compositions may be cast into a desired shape by dispensing the mixture onto a suitably shaped substrate. In those cases where a dressing conforming to the shape of a particular wound or body surface is required, it is most convenient to dispense the mixture directly onto the wound or body surface and to allow the composition t cure *in situ* to form the dressing. If desired, stiffening or supporting materials, for xample one or more gauze layers or a sleev , may be introduced into the mass of mixed composition before completion of curing of the composition to increase the stiffness r durability f the dressing.

In order that the invention may be more fully understood there now follows a description of selected illustrative example methods of making dressings provided by the invention.

In the drawings, Figure 1 is a schematic diagram showing a "can-in-can" type of package and Figure 2 is a schematic diagram showing a "can-on-can" type of package.

Each of the curable compositi ns hereinafter referred t comprise tw components and is capable of curing at room temperature of 18.5° ± 3°C when the components are mixed to provide a w und dressing.

Example comp sitions 1 to 5 pr vided parts A for admixture with catalyst to provide a resilient foam. The comp sitions comprised the following materials in the amounts by weight shown:

Material	*Example Composition* 1	2	3	4	5
α,ω Hydroxy polysiloxane 1	100	100	100	100	50
α,ω Hydroxy polysiloxane 2	-	-	-	-	50
Low molecular weight hydroxy siloxane 1	10	10	50	50	10
Low molecular weight hydroxy siloxane 2	-	-	-	-	15
Alkylhydrogensiloxane 1	10	20	10	10	10
Crosslinking agent	4	4	4	4	4
Vinyldimethyl silanol Chain terminator	-	-	5	-	-
diphenylmethyl silanol	10	10	-	-	-
heptamethyltrisiloxan-2-ol	-	-	-	-	7.5
nonamethyltetrasiloxan-1-ol	-	-	-	10	-
Filler	10	10	15	15	10

The α,ω hydroxy polysiloxanes 1 and 2 used were polydimethylsiloxanes having viscosities at 25°C of 2 Pa.s and 13.5 Pa.s respectively (i.e. molecular weights 21000 and 40,000 respectively) together with minot amounts of cyclic polydimethylsiloxanes.

The low molecular weight hydroxy siloxane 1 comprised α,ω hydroxy polydimethylsiloxanes having 1 to 23 siloxane units. The low molecular weight siloxane 2 comprised dihydroxy polydimethyl polymethyl vinylsiloxanes having an average of about 3.5 dimethylsiloxane units per molecule and about 2 methylvinyl siloxane units per molecule respectively.

The alkylhydrogen siloxane 1 used was a mixture of trimethylsiloxy end blocked methylhydrogen polysiloxanes having a viscosity at 25°C of about 0.02 to 0.04 Pa.s and an SiH content (as H) of about 1.6%.

The crosslinking agent used was n propyl ortho silicate.

The filler used was Wacker H2000 which is understood to be a material prepared by treatment of finely divided silica and hexamethyldisilazane to provide a hydrophobic silica having a surface area of 170±30 m^2/g and a silica content not less than 97%.

Each of the example compositions was aged at 62°C for eight weeks. There was no evidence of separation of any of the compositions. Each of the compositions, when mixed with 6% (by weight of the example composition) stannous octoate foamed within five minutes to provide a substantially open cell foamed product which cured to a resilient cellular product.

Example 1

Example compositions 1, 2, 3, 4 and 5 were packaged in "can-in-can" packages (Figure 1) in the following way. 1.8g stannous octoate were charged to a compartment provided by a frangible capsule in the form of a glass tube (10) containing a steel rod (12). A mixture of compressed nitrogen gas and 2 parts by volume liquid pentane was introduced to the glass tube under a pressure of 7 bars, and the tube was sealed about the rod. 30g of the part A of the composition were placed in a compartment provided by a metal container (14) and the sealed tube placed into the part A within the metal container thus to provide a package with an inner (16) and an outer (18) chamber, the inner containing the catalyst or part B and the outer containing the part A. The metal container was sealed with a cap (20) including a discharge valved nozzle (22) and provision for actuating the rod to release the content of the inner chamber for admixture with the contents of the outer chamber. When it was desired to dispense the contents of the package, the can was inverted, the rod (12) was actuated to permit the catalyst, nitrogen and pentane to come into contact with the part A and the package was shaken to mixt the materials. The valve was operated to permit release of the mixed materials from the package via the nozzle (22) under pressure exerted by the gases present in the mixture.

Each of the example compositions was thus dispensed as a bead of mixed composition into an open wound. The package was moved in rder to dispense a mass f th material in the location required, until the package had been at least substantially empti d. The beam foamed to some extent as it was dispens d, and the foam forming and curing reactions were at least substantially complet d within about 5 minutes of expulsion of the material to provide a dressing in the form of a crosslinked polysiloxane foam mass of a shape complementary to that of the wound.

Example 2

Example compositions 1, 2, 3, 4 and 5 were packaged in a "can-on-can" package (Figure 2) in the following way. 8g stannous oct ate catalyst was charged to a metal container (30) together with 4g of a liquid, which was intended to subsequently provide propellant gas for expulsion with the composition, namely Freon 12.

The container was closed by use of a one way valve (32) and its outlet screwed into a first port (36) of a manifold block (34). 100g of the example composition (Part A) was charged to a compartment provided by a metal container (40) having a membrane lining (42) secured adjacent an outlet of the container. The container contained, between the container and the membrane, 10g of liquid which was intended to subsequently provide propellant gas pressur to act upon the membrane and so dispense the composition. The container was closed by use of a one way valve (44) and its outlet screwed into a second port (38) of the manifold block. The first (36) and second (38) ports of the manifold block were arranged to deliver from the manifold, upon actuation of the one way valves, volumes of the Part A and catalyst-Freon mixture proportioned according to the desired mixing ratio of the components i.e. 100 parts by volume Part A to 6 parts by volume catalyst. Composition delivered from the manifold was discharged through a nozzle (46) of the disposable static mixer type. When it was desired to dispense material from the package, the containers were moved relative to the manifold to actuate both one way valves (32, 44). The propellant gas in each container caused composition from each can (30, 40) to flow into the manifold block (34) and through the first and second ports (36, 38) and the nozzle (46). The components were thus proportioned by the gas pressures and the ports and mixed by the static mider in absence of air. Mixed composition was directed into an open wound. When a desired amount of the composition had been dispensed, the containers were allowed to move from the manifold to close the ne way valves (32, 44). In preparation for a subsequent dispensing operation, the nozzle was removed and replaced with another.

Composition dispensed from the nozzle was in the form of a bead which cured within 3 minutes of discharge from the nozzle to provide a crosslinked polysiloxane mass of a shape complementary to that of the wound. Each of the beads commenced foaming within 10 seconds of its exit from the static mixer. Sufficient composition was dispensed to provide a dressing for the wound.

CLAIMS

1. A method of making a medical dressing by use of a room temperature curable polysiloxane composition comprising two component parts which together provide an organosilicon polymer including siloxane units providing a silicon-bonded hydroxyl group, an organosilicon polymer including siloxane units having a silicon-bonded hydrogen atom, filler material and catalyst, the organosilicon polymers being such that they are capable of chemical reaction at room temperature when mixed in the presence of the catalyst whereby hydrogen is evolved to cause the composition to foam and the composition become cured thus to provide a resilient polysiloxane foam mass which method comprises procuring a package comprising two compartments each of which contains one of the component parts of the composition and from which the component may be expelled by means of propellant gas, in which package the filler material comprises finely divided hydrophobic filler and at least one of the components also contains a material intended to provide a propellant gas, the package being so constructed and arranged that it may be operated to mix predetermined proportions of the components in the absence of air and to dispense the mixed composition from the package, the method also comprising operating the package to bring about mixing of the components in said predetermined proportions and dispensing the mixed composition from the package to provide said dressing in desired shape.

2. A method according to Claim 1 further characterised in that the filler is a product of the treatment of finely divided silica with hexamethyl disilazane in presence of water and has a surface area between about 100 and 250 square metres per gram.

3. A method according to either one of claims 1 and 2 further characterised in that one of the compartments contains a component comprising the cataiyst and said material intended to provide a propellant gas.

4. A method according to Claim 3 further characterised in that the other of the compartments contains within a membrane in the compartment a component comprising the other ingredients of the composition, there being propellant located between the membrane and an element of the compartment whereby the membrane may be caused by the propellant gas to expel the component when required.

5. A method according to any one of the preceding claims further characterised in that the package is provided with a mixer nozzle through which the predetermined proportions of the components are dispensed.

6. A method according to Claim 3 further characterised in that said one of the compartments is frangible and is located within an outer compartment containing a component comprising the other ingredients of the composition, the package also having means for permitting the components to become mixed prior to dispensing the mixed composition.

7. A method f preparing a medical dressing substantially as hereinbefore described with reference to (a) Example 1 or (b) Example 2.

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